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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,598	06/03/2005	Andreas Meisel	BB-117	1867

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EXAMINER	
ROBERTS, LEZAH	
ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
06/24/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/506,598	MEISEL ET AL.	
	Examiner	Art Unit	
	LEZAH W. ROBERTS	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-32* is/are pending in the application.

4a) Of the above claim(s) *19 and 26-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-18 and 20-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in Response the Amendment filed March 26, 2008. All previous rejections have been withdrawn unless stated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This Action is made NON-FINAL.

Claim Rejections - 35 USC § 112 – Scope of Enablement (New Rejection)

Claims 15-18 and 20-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of therapy after acute stroke, does not reasonably provide enablement for preventive therapy. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

> To be enabling, the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993). Explaining what is meant by "undue experimentation," the Federal Circuit has stated that
>
> > The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. PPG v. Guardian, 75 F.3d 1558, 1564 (Fed. Cir. 1996).[1]

[1] As pointed out by the court in In re Angstadt, 537 F.2d 498, 504 (CCPA 1976), the key word is "undue", not "experimentation".

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the nature of the invention,
2) the breadth of the claims
3) the relative skill of those in the art,
4) the state of the prior art,
5) the predictability of the art,
6) the amount of direction or guidance provided,
7) the presence or absence of working examples, and
8) the quantity of experimentation necessary.

These factors are always applied against a background understanding that scope of enablement varies inversely with the degree of unpredictability involved. In re Fisher, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping that in mind, the Wands factors are relevant to the instant fact situation for the following reasons.

The instant specification fails to provide guidance that would allow the skilled artisan to practice the instant invention without resorting to undue experimentation, as discussed in the subsections set forth infra.

1) *The nature of the invention.* The invention discloses a method for preventive anti-infective therapy after acute stroke with at least one anti-infective agent and/or at least one immunomodulating agent.

2) *The breadth of the claims.* The claims are broad because they read on "preventive".

3) *The relative skill of those in the art.* The relative skill of those in the art are PhD, MD, and MS.

4) *The State of the Prior Art.* The prior art discloses anti infective agents such as antibiotics treats certain infections depending on the drug and the type of infection.

5) *The Predictability or Lack Thereof in the Art.* The term preventive may encompass different meanings such as preventing one from ever getting a particular infection or preventing the infection from progressing. The claims suggest that one will never get an infection after a stroke when taking any anti-infective agent and/or at least one immunomodulating agent. Prevention is not practical with infections after a condition such as stroke. Especially considering the independent claim does not give any indication as to what drug is used and what infection is being prevented or treated. The infections disclosed by the dependent claims include urinary tract, pneumonias and sepsis. It cannot be predicted that all anti-infectives will prevent or even treat these three types of infections, let alone all infections, especially considering that organisms causing these infections may mutate and become resistant to certain medicinal agents. In the case of mutation, it cannot be predicted if a specific agent can treat one condition

in all individuals. Anti-infectives have different mechanisms of action (Drug Actions: Basic Principle and Therapeutic Aspects, October 1995). Some do not kill the pathogen and only inhibit the proliferation of the microorganisms while others lead to a reduction of the number of pathogens. They work in conjunction with the host's defense system. Other factors play a role in treating infection such as genetics, the change in pH at the infected cite, and abscesses or necroses. Some viruses cannot be prevented and therefore anti-infective therapy would not work on these viruses. Therefore it cannot be predicted that all anti-infective agents and/or immunomodulating agents will be successful in treating all the conditions that may occur after a stroke. Experimentation must be done to determine which compounds are suitable for treatment of a condition and the amount needed to be administered. It must also be taken into account when using a mixture of agents as encompassed by the claims, what effect this will have on the infection such as side effects or unnecessary development of resistance (page 518, second col., Drug Actions).

6) *The Amount of Direction or Guidance Present/The Presence or Absence of Working Examples.* The disclosure teaches administration of certain drugs inhibited infection, such as pneumonia and bacteraemia as developed in subjects that did not receive therapy. The drugs reduced certain events such as fever/hyperthermia and in particular the lethality after stroke. Examples included administering a combination of mezlocillin and sulbactam; imipenem and cilastatin; and moxifloxacin. The disclosure also discusses the effect of certain agents, such as IFN-gamma and propranolol,

separately, on reduction in the number of lymphocytes and the effect on a subject. Without treatment the number of lymphocytes decreases causing different events such as pneumonia. IFN-gamma reduced both germ number in the lungs and blood. Propranolol inhibited infections and improved survival after stroke. It appears from the data that not all the studies show total prevention as encompassed by the instant claims.

7) *The Quantity of Experimentation Needed.* The applicant needs to provide examples of using a representative set of all the compounds encompassed by the instant claims showing the subject never develops the conditions that are encompassed by the independent claim and the three recited in the dependent claims, urinary tract, pneumonias and sepsis.

Claim Rejections - 35 USC § 103 – Obviousness (Previous Rejection)

Claims 15-18 and 20-25 were rejected under 35 U.S.C. 103(a) as being unpatentable over Fong (The Journal of Infectious Diseases, 2000, Vol. 181, Suppl. 3, pp. S514-S518 as cited in the IDS) in view of Vlasselaer et al. (US 2001/0043906). The rejection is maintained.

Applicant's Arguments

The present invention provides methods for preventive anti-infective therapy after acute stroke. Therapy starts at a point in time when a stroke has occurred but a bacterial infection has not yet occurred in the patient. Both Vlasselaer et al. and Fong refer to the treatment of an infection, i.e. administration of an active compound after the onset of a bacterial infection. There is no suggestion in these references of applying treatment in the absence of an established infection. In contrast to the cited references, the current invention provides methods for preventing debilitating infections that so often occur after an acute stroke. Through the early administration of a preventive anti-infective therapy (in the case of moxifloxacin preferably within the first 24 hours) in accordance with the subject invention, lethality and the neurological deficit are drastically reduced. In a further aspect of the invention, it is possible to prevent the development of infections by means of immunomodulating agents such as beta-blockers or by the administration of IFN-7. It is well established in the patent law that the mere fact that the purported prior art could have been modified or applied in some manner to yield applicant's invention does not make the modification or application obvious unless the prior art suggested the desirability of the modification. In re Gordon, 221 USPQ 1125, 1127 (Fed. Cir. 1984). Moreover, as expressed by the CAFC, to support a § 103 rejection, "[b]oth the suggestion and the expectation of success must be founded in the prior art ..." In re Dow Chemical Co. 5 USPQ 2d 1529, 1531 (Fed. Cir. 1988). As is clearly shown by the foregoing remarks, one finds neither the suggestion nor the expectation of success in the cited references, either separately or combined. An assertion of obviousness without the required suggestion or expectation of success

in the prior art is tantamount to using applicant's disclosure to reconstruct the prior art to arrive at the subject invention. Hindsight reconstruction of the prior art cannot support a § 103 rejection, as was specifically recognized by the CCPA in In re Sponnoble, 56CCPA 823, 160 USPQ 237, 243 (1969). This Argument is not persuasive.

Examiner's Response

Although the claims read on preventing, this encompasses not only preventing something from ever occurring but also encompasses preventing something from progressing as in the case of the references. Therefore the references encompass the instant claims as written. Applicant also argues that "lethality and the neurological deficit are drastically reduced". This suggests that complete prevention is not achieved and the compounds are not only preventing but also treating. The reference suggests giving the disclosed agents for "preventing" these conditions when it discloses that the compounds treat the conditions. It would be in the relative skill in the art to administer a specific anti-infective agent to a patient that is at high risk of developing a condition to inhibit the condition with a high expectation of success. Especially when that agent is know to treat the specific condition. In regards to hindsight reasoning, as stated previously it is would not be unreasonable for one of skill in the art to use a compound known to treat a condition and to use it for inhibiting the formation or progression of the condition.

Claims 15-18 and 20-25 are rejected.

Claims 19 and 26-32 are withdrawn.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612